DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard
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December 21, 1999

Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
U.S. Patent and Trademark Office
2121 Crystal Drive
Crystal Park 2, Suite 906
Arlington, Virginia 22202

Dear Commissioner Dickinson:

I wish to extend my appreciation for your visit to the National Institutes of Health (NIH) to review the proposed Revised Written Description and Revised Utility Guidelines. The comments that follow provide a brief technical analysis regarding specific aspects of the proposed Revised Utility and Written Description Guidelines for the purpose of expanding upon certain concerns and comments discussed generally in the accompanying communication. As you know, our primary concern is that patents of broad scope for genes and gene fragments of undisclosed biological function may hinder, rather than promote, beneficial advancements in the important area of medical genetics and health policy.

As indicated in the accompanying letter, we strongly support the three-pronged test for utility proposed in the Revised Utility Guidelines. The NIH urges that this guideline requiring that a claimed invention possess a specific, substantial, and credible utility be applied in all cases, including situations where the invention is deemed to possess a "well-established" utility.

The proposed Revised Utility Guidelines acknowledge a category of utility that is not affirmatively asserted in the patent application but, nonetheless, is defined as a "well established" utility. Logic dictates that "well established" utilities must also satisfy the requirements to be specific, substantial, and credible. Toward this end, a Patent and Trademark Office (PTO) rejection alleging failure to assert a specific and substantial utility may be rebutted by evidence that the claimed invention possesses a specific and substantial utility that was "well established" at the time of filing. Consequently, the record would be clear as to the identity and nature of this alleged "well established" utility.

However, the PTO may rely upon a "well established" utility under two additional sets of circumstances. One circumstance arises when the PTO itself deems a claimed invention possesses a "well established" utility absent any assertion by applicant of a specific and substantial utility. The other circumstance arises when applicant asserts

utilities deemed neither specific nor substantial, but the PTO envisages the existence of an undisclosed "well established" utility. Unlike the situation where the PTO challenges applicant to identify and justify a "well established" utility, the proposed Revised Guidelines do not require the PTO address on the official record the identity or considerations underlying the specificity and substantiality of any "well established" utilities it accepts *de novo*.

An incomplete and ambiguous official record arising from silent acceptance of a "well established" utility is an unnecessary burden on patents in a complex art already over-burdened with controversial issues. Where a "well established" utility is relied upon to satisfy the utility requirement, the record should be complete and clear regardless who makes the assertion. Therefore, we strongly encourage the PTO to resolve this simple, but potentially serious, oversight in the Revised Guidelines by requiring complete disclosure supporting allegations or conclusions of "well established" utility by either the applicant or the Patent Examiner.

The NIH has also followed with interest the development of the new Revised Guidelines on Written Description. Similar to our concerns regarding utility, the NIH believes there may be potentially serious adverse consequences to the public health and biotechnology research communities in granting patent claims of broad scope on certain gene and partial gene sequences. From the patentabililty perspective, these concerns involve issues of written description and enablement. As communicated by the NIH and many other respondents, the original proposed Written Description Guidelines raised significant patentability issues in this area when disclosed nucleic acid sequences are claimed using open-ended transitional claim language, such as "comprising."

While the newly proposed Revised Written Description Guidelines address some aspects of this issue, the relationship of claim transition language to the scope and written description of nucleic acid sequences still requires clarification in order to adequately address the concerns of the NIH. For example, an anonymous nucleic acid sequence claimed with open language may be interpreted to also encompass any full-length gene containing the claimed subsequence. The concerns of the NIH regarding the potential chilling consequences such an interpretation may have on research and development of genomic products for the public health has been documented in our previous communications.

The Court of Appeals for the Federal Circuit (CAFC) has consistently instructed that nucleic acid sequences be treated under the patent statutes similarly to other chemical compounds. Consequently, the disclosed structural formula (sequence) of a nucleic acid should not be altered in indiscriminate and incalculable ways through choice of transition claim language. By contrast, it is well accepted that open transition phrases, such as "comprising" may broaden the scope of a composition claim by permitting unrecited subject matter to be <u>in combination</u> with the expressly recited subject matter (i.e., chemical or nucleic acid formula).

The newly proposed Revised Written Description Guidelines appear to address this issue by providing endnote definitions for transition terms consistent with general chemical patent practice. Universal application of these definitions to nucleic acid and protein sequence claims would be consistent with the recurrent instructions from the CAFC noted above. This would be consistent also with the Revised Guideline's stated goal that "[t]ransition phrases should be given the same treatment in all cases." Indeed, adoption of such traditional chemical practice usage and meaning for transition phrases in nucleic acid claims would go a long way toward ameliorating the concerns of the NIH in this area.

However, the Revised Written Description Guidelines respond to various comments regarding EST issues in a manner that appears to undermine a clear and consistent resolution of this important consideration. It appears from the responses to comments that the revised guidelines again adopt an interpretation of open "comprising" transition language that would permit holders of patents to anonymous sequence fragments to assert domination over later discovered full-length genes. Such domination may encumber and hinder the development of later discovered genetic information of significant medical consequence. Additionally, recently issued patents claiming partial DNA sequences merely add to this ambiguity, and belie the tone of our discussions to overcome the NIH concerns with these issues

The NIH found our recent discussions with the PTO useful toward understanding our respective missions. It appears the PTO wishes to establish guidelines to address and satisfy NIH and industry concerns related to patenting of genes and gene fragments. This common goal may be advanced significantly by eliminating or amending responses to comments that confuse the clear meaning of the endnote definitions for transition terms. Residual ambiguity regarding this issue should be removed by clear statements from the PTO in the final guidelines confirming the consistent application of chemical practice definitions of transition terms, consistent with the endnotes, to claims reciting nucleic acid and protein sequences. As enumerated in the accompanying letter, the NIH remains open and ready to engage in further constructive discussions toward clarifying the perceived ambiguities in the proposed Revised Utility and Revised Written Description Guidelines.

/s/

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